REMARKS

Applicants have studied the Office Action mailed February 14, 2006. It is respectfully submitted that the application is in condition for allowance. Reconsideration and allowance of the pending claims in view of the following remarks is respectfully requested.

Rejection of claims 3, 24, and 31-32 under 35 USC §102(b):

The Examiner rejected claims 3, 24, and 31-32 under 35 USC §102(b) as being anticipated by Miernyk et al.

In making this rejection, the Examiner states that Miernyk et al. teaches a polyclonal antibody to a 14 amino acid fragment of pyruvate dehydrogenase, which is the same as amino acids 296-310 of SEQ ID NO:2 in the instant application. The Examiner asserts that, therefore, the antibody taught by Miernyk et al. would bind to SEQ ID NO:2 of the instant application. The Examiner also states that claims 31-32 are included because the buffer solution associated with the antibody is considered a form of a pharmaceutically acceptable carrier.

In response, Applicants respectfully assert that Miernyk et al. does not anticipate claims 3, 24, and 31-32.

The Examiner asserts, in effect, that the antibody taught by Miernyk et al. will inherently cross-react and thus bind to the same polypeptides (i.e., polypeptides comprising or consisting of SEQ ID NO:2) as the instantly claimed antibodies, thereby anticipating the instant claims. However, inherency may only be relied upon where the consequences of following the reference disclosure always necessarily results in the claimed invention. If there is not a reasonable certainty that the claimed subject matter will necessarily result, the rejection is not proper.

Specifically, in order for the antibody of Miernyk et al. to inherently anticipate the instant claims, the antibody of Miernyk et al. must necessarily selectively bind to the polypeptides recited in the instant claims (i.e., polypeptides comprising or consisting of SEQ ID NO:2). It is not sufficient that the antibody of Miernyk et al. may possibly or probably bind to the polypeptides recited in the instant claims.

However, this "possibly or probably" standard appears to be the standard that the Patent Office is relying on for the rejection of claims 3, 24, and 31-32 under 35 USC §102(b). The Examiner has cited a reference that teaches an antibody that may possibly or probably selectively

bind to polypeptides of SEQ ID NO:2 because the reference antibodies bind to a short peptide that has an amino acid sequence that corresponds to a small fragment of SEQ ID NO:2 (corresponding only to residues 296-310 of SEQ ID NO:2), without demonstrating that the reference antibodies must necessarily selectively bind to polypeptides of SEQ ID NO:2.

It is Applicant's position that the antibody of Miernyk et al. does not necessarily selectively bind to polypeptides of SEQ ID NO:2 because different epitopes must necessarily exist in the protein of SEQ ID NO:2 compared with the pyruvate dehydrogenase fragment of Miernyk et al. because of the differences that exist in their amino acid sequences. For example, the amino acid sequence of instant SEQ ID NO:2 differs from the pyruvate dehydrogenase fragment of Miernyk et al. at least over amino acid residues 1-295 and 311-397 of SEQ ID NO:2. Therefore, due at least to these differences in the protein structures, the antibody taught by Miernyk et al. does not necessarily cross-react with the same proteins (i.e., proteins comprising or consisting of SEQ ID NO:2) as the antibodies of claims 3, 24, and 31-32.

Accordingly, Applicants respectfully request that the rejection of claims 3, 24, and 31-32 under 35 USC §102(b) be reconsidered and withdrawn.

Rejection of claims 3 and 24-30; 31-32; 33-34; and 35-36 under 35 USC §103(a):

The Examiner rejected claims 3 and 24-30 under 35 USC §103(a) as being unpatentable over Miernyk et al. in view of Harlow et al. (I) (however, Applicants note that the inclusion of claims 3 and 24 in this rejection under 35 USC §103(a) appears to be an error); rejected claims 31-32 under 35 USC §103(a) as being unpatentable over Miernyk et al. in view of Harlow et al. (II); rejected claims 33-34 under 35 USC §103(a) as being unpatentable over Miernyk et al. in view of Harlow et al. (I) as applied to claims 3 and 24-26 above and further in view of Harlow et al. (II); and rejected claims 35-36 under 35 USC §103(a) as being unpatentable over Miernyk et al. in view of Harlow et al. (III).

In making these rejections, the Examiner states, in summary, that (with respect to claims 25-26) Harlow et al. (I) teach that monoclonal antibodies can be made by fusing B cells from an animal immunized with an antigen with myeloma cells; that (with respect to claims 27-30) Harlow et al. (I) teach that antibodies can be readily labeled by covalent coupling to enzymes and a large number of enzymes have been used to label antibodies, such as alkaline phosphatase and β-galactosidase; that (with respect to claims 31-32) Harlow et al. (II) teach that antibodies in

compositions comprising phosphate buffered saline (PBS) can be used for immunohistochemical techniques, and (with respect to claims 33-34) this can be applied to monoclonal antibodies as taught by Miernyk et al. and Harlow et al. (I); and that (with respect to claims 35-36) Harlow et al. (III) teach that antibodies can be cleaved into Fab and $F(ab')_2$ fragments. The Examiner asserts that, therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make these compositions, and one of ordinary skill in the art would have been motivated to do so and would have had a reasonable expectation of success.

However, in light of the discussion above in regards to the anticipation rejection under 35 USC §102(b) in view of Miernyk et al., it is clear that Miernyk et al., even in combination with any of Harlow et al. (I), Harlow et al. (II), and/or Harlow et al. (III) neither anticipates nor makes obvious any of claims 3 and 24-30; 31-32; 33-34; and 35-36 due at least to the different epitopes that necessarily exist because of the significant differences between the pyruvate dehydrogenase fragment of Miernyk et al. compared with the protein of SEQ ID NO:2 of the instant application (for example, SEQ ID NO:2 differs from the pyruvate dehydrogenase fragment of Miernyk et al. at least over amino acid residues 1-295 and 311-397 of SEQ ID NO:2). This obviates the teachings of Harlow et al. (I), Harlow et al. (II), and Harlow et al. (III) with respect to Miernyk et al. as it applies to claims 3 and 24-30; 31-32; 33-34; and 35-36 under 35 USC §103(a).

Accordingly, Applicants respectfully request that these rejections under 35 USC §103(a) be reconsidered and withdrawn.

Conclusions

Claims 3 and 24-36 remain pending and under consideration. Claims 1-2 and 37-38 were withdrawn from consideration by the Examiner as being drawn to a nonelected invention.

In view of the above remarks, Applicants respectfully submit that the application and claims are in condition for allowance, and request that the Examiner reconsider and withdraw the rejections. If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned agent at (240) 453-3812 should the Examiner believe a telephone interview would advance prosecution of the application.

Respectfully submitted,
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